REMARKS

Claims 23-24, 27, 32-36, 39, 44-46 and 66-137[1] are pending in the present application. By this amendment, Claims 134-137 are added, no claims are amended, and no claims are cancelled. Applicants respectfully request reconsideration of the present claims in view of the following remarks.

On November 10, 2003, an interview with Examiner Nasser took place with Shelby Grier, Attorney for Applicants; George Metzenthin, Attorney for Applicants; Justin Hartings, Inventor/Applicant; and Chad Roy, Inventor/Applicant. The Interview Summary provided by the Examiner was reviewed and is accurate. The statements set forth below summarize what was discussed during the interview.

Applicants submit that new Claims 133-137 are allowable over the cited art based on the reasons stated herein, and the discussion during the interview with the Examiner.

Response to Claim Rejections Under 35 U.S.C. §102(b)

Turning now to the Official Action, Claims 23, 27, 35, 39, 68, 69, 71, 72, 80, 84, 102, 103, 105, 106, 114 and 117 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,674,490 to *Frankel et al.* (hereinafter *Frankel*). This rejection is respectfully traversed.

Frankel discloses an apparatus for aerosol immunization of subjects including an aerosol exposure chamber having controlled humidity, apparatus for providing a

[1] The listing of claims in item 4 of the Office Action Summary omitted Claim 35.

precisely controlled spray of vaccine in the exposure chamber at a predetermined droplet median diameter and feed rate, and apparatus for continuously supplying the subjects to and removing them from the chamber for aerosol treatment. The system discloses in *Frankel* also includes apparatus for maintaining the relative humidity in the exposure chamber in the vicinity of 100% to prevent significant evaporation of water droplets containing the vaccine which could cause such droplets to shrink to within the respiration range of the subjects, thus harming them. Col. 2, lines 3-18.

Independent Claim 23 of the present invention describes a method including the steps of automatically controlling an environment of an inhalant chamber, and automatically controlling a concentration of an inhalant in the inhalant chamber.

Independent Claim 35 of the present invention describes a system including means for automatically controlling an environment of an inhalant chamber, and means for automatically controlling a concentration of an inhalant in the inhalant chamber.

The *Frankel* patent fails to disclose, teach or suggest a method or means for automatically controlling the concentration of an inhalant in an inhalant chamber as claimed in the present application. In contrast to the present invention, the system disclosed in *Frankel* delivers an aerosol to a chamber wherein the aerosol droplets have a predetermined median diameter. Col. 2, lines 3-10. The aerosol droplet size determines the location of deposition in the respiratory tract for an inhaled substance. The system disclosed in *Frankel* maintains a near 100% humidity within the vaccination chamber for the purpose of maintaining a large aerosol droplet size. Col. 1, lines 24-40; Col. 2, lines 12-18.

The *Frankel* invention also uses a predetermined feed rate to maintain a large aerosol droplet size; however the concentration of the aerosol is not automatically controlled. Aerosols can have varying concentrations at large diameters or small diameters. Simply because the diameter of the aerosol is maintained at a particular size, does not mean that the concentration of the aerosol is controlled or maintained in any manner. *Frankel* states at Col. 4, lines 65-68 that a solenoid valve is opened in order to provide the desired aerosol spray due to impingement of the diluted vaccine at a predetermined flow rate on a spinning disc. The volume median diameter size of the aerosol droplets is a function of the disc dimension and configuration, its speed of rotation, the properties of the liquid being atomized and the feed rate of the liquid to the disc. Col. 5, lines 45-49. Of the factors *Frankel* mentions, only the feed rate of the diluted vaccine to the disc can be changed during operation to affect the median diameter of the aerosol droplets. Thus, the feed rate must be at a predetermined value in order to establish a desired droplet medium diameter, which is the objective of the *Frankel* patent. The Examiner asserts that the concentration of vaccine in the chamber is automatically controlled because the feed rate is predetermined. However, if the feed rate is set at a predetermined value to establish median diameter of the droplets, the feed rate cannot be adjusted to automatically control the concentration in the chamber because that would change the droplet size.

Furthermore, the vaccination system disclosed in *Frankel* does not include any form of sensor, monitor or diagnostic to measure the concentration of vaccine in the chamber. As discussed during the interview with the Examiner, the ingestion of vaccine

by chicks within the inhalation chamber, causes the concentration of vaccine within the chamber to vary. Frankel provides no means for monitoring or compensating for this variance in concentration. In order to automatically control the concentration in the vaccination chamber, a measurement of the concentration must be obtained. Accordingly, it is not possible for the concentration to be automatically controlled in the vaccination system disclosed in *Frankel*.

The present invention overcomes this limitation. One exemplary embodiment does this, by providing a secondary flow of air into the inhalation chamber as well as automatically controlling the aerosol generation device, the airflow rate or feed rate to the generation device is automatically adjusted based on a reading from the concentration monitor or other monitors as described at page 20, line 19 to page 22, line 8 of the specification. The present invention provides for a full range of automatic concentration and environmental control through the use of a variety of system inputs.

For at least the reasons given above and based on the discussion during the interview, Applicants respectfully submit that independent Claims 23, 35 and 134-137 are allowable over *Frankel*. Since Claims 27, 39, 68, 69, 71, 72, 80, 84, 102, 103, 105, 106, 114 and 117 depend from independent Claim 23 or 35 and recite additional claim features, Applicants further submit that Claims 27, 39, 68, 69, 71, 72, 80, 84, 102, 103, 105, 106, 114 and 117 are allowable over *Frankel*.

Appl. No. 09/919,741
Amdt. dated November 14, 2003
Reply to Office action dated July 15, 2003

Response to Claim Rejections Under 35 U.S.C. §102(e)

Claims 23, 25, 35, 39, 68, 69, 71, 72, 80, 81, 83, 86, 102, 103, 105, 106, 114, 115, 117 and 120 are rejected under 35 U.S.C.102(e) as being anticipated by U.S. Patent No. 6,263,872 to *Schuster et al.* This rejection is respectfully traversed.

The *Schuster* patent discloses a portable device for controlling the temperature of the air surrounding an aerosolized drug formulation. The temperature controlling device is comprised of a heating element which warms the air surrounding the pharmaceutical formulation. The warming of the air results in evaporating liquid carrier from aerosol particles of a liquid formulation, thereby obtaining a smaller, more uniform particle size. The invention may include a control circuit, a temperature sensing means and a relay. Col. 1, lines 39-46, lines 62-65.

As stated above, independent Claim 23 describes a method wherein a concentration of an inhalant in an inhalant chamber is automatically controlled. Similarly, independent Claim 35 describes a system including a means for automatically controlling a concentration of an inhalant in an inhalant chamber. The *Schuster* patent fails to disclose, teach or suggest such a method or system.

The differences between the present invention and the *Schuster* patent are many, and mostly result from the *Schuster* patent being targeted to a completely different market than the present invention. Specifically the *Schuster* invention involves technology related to metered dose inhalers (MDI). With an MDI device, a single "puff" or dose of an inhalant must be prepared (at the volume, temperature, humidity, etc.) for a single inhalation - vent, i.e. breath for the subject. The device disclosed in the

Schuster patent simply heats a volume of air to a predetermined temperature, and then injects an aerosol through said volume in order to reduce the size of the aerosol particles before being inhaled by a user. Col. 3, lines 40-46; Col. 16 line 66 to Col. 18 line 3. The device includes a disposable package having a plurality of disposable containers. Each container comprises a drug formulation that is aerosolized and released through a cylinder during a single inhalation event. Col. 15, line 66 – Col. 16, line 8, lines 39-46.

In the *Schuster* invention, upon actuation by a user, a single predetermined dose of a drug formulation passes through a cylinder, is heated to a predetermined temperature and is then inhaled by the user. There is no mention or suggestion in the *Schuster* patent for measuring or automatically controlling the concentration of the aerosol within the cylinder. The aerosol dosage is predetermined by the amount of drug formulation within each disposable container. Thus, it is not necessary to maintain or measure the concentration of the aerosol passing through the cylinder. Furthermore, since the aerosol simply flows through the cylinder during a given inhalation event, it is not possible to maintain a given concentration of aerosol within the cylinder.

During the interview with the Examiner, the Examiner acknowledged that the cylinder disclosed in *Schuster* is not an inhalation chamber as described in the present invention.

In contrast to *Schuster,* the present invention automatically controls the concentration of an inhalant within a chamber. In the present invention, the airflow rate or feed rate to the generation device is automatically adjusted based on a reading from

a concentration monitor or other concentration-related sensors including a chamber pressure monitor, an inhalant-concentration sensor, a gas sensor, an input airflow sensor, and/or an output airflow sensor. *See* page 20, line 19 to page 22, line 8 of the specification. The present invention provides for a full range of automatic concentration and environmental control through the use of a variety of system inputs.

For at least the reasons given above and based on the discussion during the interview, Applicants respectfully submit that independent Claims 23, 35 and 134-137 are patentable over *Schuster et al.* Since Claims 25, 39, 68, 69, 71, 72, 80, 81, 83, 86, 102, 103, 105, 106, 114, 115, 117 and 120 depend from either Claim 23 or 35 and recite additional claim features, Applicants further submit that Claims 25, 39, 68, 69, 71, 72, 80, 81, 83, 86, 102, 103, 105, 106, 114, 115, 117 and 120 are patentable over *Schuster.*

Response to Claim Rejections Under 35 U.S.C. §103(a)

Claims 70, 73, 104 and 107 are rejected under U.S.C. 103(a) as being unpatentable over *Frankel.* This rejection is respectfully traversed.

As explained in detail above, the *Frankel* patent does not disclose, teach or suggest the automatic control of an inhalant concentration within an inhalant chamber as recited in independent Claims 23 and 35. Since Claims 70, 73, 104 and 107 depend from independent Claim 23 or 35 and recite additional claim features, Applicants further submit that Claims 70, 73, 104 and 107 are patentable over *Frankel.*

Appl. No. 09/919,741
Amdt. dated November 14, 2003
Reply to Office action dated July 15, 2003

Claims 70, 73, 104, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Schuster*. This rejection is respectfully traversed.

As explained above, the *Schuster* patent fails to disclose, teach or suggest the automatic control of an inhalant concentration within an inhalant chamber as recited in Claim 23 or 35. Since Claims 70, 73, 104 and 107 depend from independent Claim 23 or 35 and recite additional claim features, Applicants further submit that Claims 70, 73, 104 and 107 are patentable over *Schuster*.

Conclusion

In view of the foregoing amendments and remarks, it is asserted that the application is in condition for allowance. Entry of this amendment and a favorable action on the merits are respectfully requested.

Respectfully submitted,

CAHN & SAMUELS, LLP

By: Shelby B. Grier

Shelby B. Grier, Esq.
Reg. No. 45,785

2000 P Street, N.W. (Suite 200)
Washington, D.C. 20036
Telephone: (202) 331-8777
Facsimile: (202) 331-3838
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